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Applicant : Carl-Axel Bauer *et al.*
Serial No. : 10/010,283
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Title : NEW USE FOR BUDESONIDE AND FORMOTEROL

Art Unit : 1617
Examiner : Jennifer M. Kim

PROPOSED CLAIM AMENDMENTS

FOR INTERVIEW WITH EXAMINER KIM AND

SUPERVISORY EXAMINER PADMANABHAN, AUGUST 23, 2005, 2:00 PM

1-8. (Canceled)

9. (Currently Amended) A method for ~~the treatment of a patient suffering from~~ reducing the frequency and/or intensity of chronic obstructive pulmonary disease (COPD) exacerbations experienced by a patient suffering from COPD, which method comprises administering to the patient via inhalation, simultaneously, sequentially or separately, ~~a therapeutically effective amount of~~ (i) a ~~dose of a~~ first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; and (ii) a ~~dose of a~~ second active ingredient which is budesonide, wherein the method is effective to reduce the frequency and/or intensity of exacerbations in the patient, and the molar ratio of the first active ingredient to the second active ingredient is from 1:2500 to 12:1.

10. (Canceled)

11. (Previously Presented) A method according to claim 9, wherein the first and/or second active ingredient is used in admixture with one or more pharmaceutically acceptable additives, diluents and/or carriers.

12. (Previously Presented) A method according to claim 9, wherein the first active ingredient is formoterol fumarate dihydrate.

13. (Previously Presented) A method according to claim 9, wherein the molar ratio of the first active ingredient to the second active ingredient is from 1:555 to 2:1.

14. (Previously Presented) A method according to claim 13 wherein the molar ratio is from 1:70 to 1:4.

15. (Currently Amended) A method according to claim 9 ~~further comprising providing the doses to the patient in the form of a dry~~, wherein the first and second active ingredients are provided in powder form.

16. (Previously Presented) A method according to claim 15 wherein the first and second active ingredients are formulated as powder particles having a mass median diameter of less than 10 μm.

17. (Previously Presented) A method according to claim 9 wherein the first and second active ingredients are provided in the form of an admixture.

18. (Currently Amended) A method according to claim 9 wherein the ~~doses~~ first and second active ingredients are administered separately, less than about 2 hours apart.

19. (Currently Amended) A method according to claim 18 wherein the ~~doses~~ first and second active ingredients are administered separately, less than about 30 minutes apart.

20. (Currently Amended) A method according to claim 19 wherein one ~~dose~~ active ingredient is administered immediately after the other.

21. (Currently Amended) A method according to claim 9 wherein the ~~amount of the dose of the~~ first active ingredient is administered to the patient in one or more unit doses per day.

the amount of the first active ingredient in each unit dose being from about 2 to 120 nmol.

22. (Currently Amended) A method according to claim 21 wherein the amount of the ~~dose of the~~ first active ingredient in each unit dose is from about 7 to 70 nmol.

23. (Currently Amended) A method according to claim 9 wherein the ~~amount of the dose of the~~ second active ingredient is administered to the patient in one or more unit doses per day, the amount of the second active ingredient in each unit dose being from about 0.1 to 5 μmol.

24. (Currently Amended) A method according to claim 23 wherein the amount of the ~~dose of the~~ second active ingredient in each unit dose is from about 0.15 to 4 μmol.

25. (Currently Amended) A method according to claim 12 wherein the ~~amount of the dose of~~ formoterol fumarate dihydrate is administered to the patient in one or more unit doses per day, the amount of the formoterol fumarate dihydrate in each unit dose being from about 1 to 50 μg.

26. (New) The method of claim 9, further comprising monitoring the number of exacerbations experienced by the patient over a period of 12 months of treatment.

27. (New) The method of claim 9, wherein the first active ingredient is administered in the form of one or more 4.5 μg unit doses of formoterol fumarate dihydrate, and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more 160 μg unit doses of budesonide.

28. (New) The method of claim 27, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered one to four times per day.

29. (New) The method of claim 9, wherein the first and second active ingredients are administered together from a pressurized metered dose inhaler (pMDI).

30. (New) The method of claim 9, wherein at least one of the first and second active ingredients is formulated in a propellant comprising one or both of P227 (heptafluoropropane) and P134(a) (tetrafluoroethane).

31. (New) The method of claim 12, wherein the first and second active ingredients are provided in admixture and are inhaled simultaneously.

32. (New) The method of claim 31, wherein the first and second active ingredients are in powder form.

33. (New) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose containing 4.5 μg formoterol fumarate dihydrate and 160 μg budesonide.

34. (New) The method of claim 33, wherein the patient is administered one to four of the unit doses per day.

35. (New) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose containing 9 μg formoterol fumarate dehydrate and 320 μg budesonide.

36. (New) The method of claim 35, wherein the patient is administered one or two of the unit doses per day.

37. (New) The method of claim 15, wherein the first and second active ingredients are provided in separate inhalers.

38. (New) The method of claim 9, wherein the first active ingredient is in the form of one or more 4.5 μg unit doses of formoterol fumarate dihydrate, and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more 80 μg unit doses of budesonide.

39. (New) The method of claim 38, wherein the unit doses of both the first active ingredient and the second active ingredient are administered one to four times per day.

40. (New) The method of claim 9, wherein the first active ingredient is administered in the form of one or more 9 μg unit doses of formoterol fumarate dihydrate, and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more 160 μg unit doses of budesonide.

41. (New) The method of claim 40, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.

42. (New) A method for the treatment of a patient suffering from COPD, which method comprises administering to the patient via inhalation, simultaneously, sequentially or separately, (i) a daily dose of 2 to 120 nmol of a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; and (ii) a daily dose of 65 to 1700 μg of a second active ingredient that is budesonide, wherein (ii) the first active ingredient is optionally in admixture with the second active ingredient, and wherein the daily dose of each active ingredient is administered in one to four divided doses per day.

43. (New) The method of claim 42, wherein each daily dose of the first active ingredient is administered as one or more 9 μg unit doses of formoterol fumarate dihydrate, and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more 320 μg unit doses of budesonide.

44. (New) The method of claim 43, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered once or twice per day.

45. (New) The method of claim 42, wherein each daily dose of the first active ingredient is administered as one or more unit doses of 4.5 μg formoterol fumarate dihydrate, and each daily dose of the second active ingredient is administered as one or more unit doses of 80 μg budesonide.

46. (New) The method of claim 42, wherein each daily dose of the first active ingredient is administered as one or more unit doses of 9 μg formoterol fumarate dihydrate, and each daily dose of the second active ingredient is one or more unit doses of 160 μg budesonide.

47. (New) The method of claim 46, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.

48. (New) The method of claim 42, wherein each daily dose of the first active ingredient is administered as one or more unit doses of 4.5 μg formoterol fumarate dihydrate, and each daily dose of the second active ingredient is administered as one or more unit doses of 160 μg budesonide.

49. (New) The method of claim 42, wherein the first and second active ingredients are administered together from a single pMDI.

50. (New) The method of claim 42, wherein at least one of the first and second active ingredients is formulated in a propellant comprising P227 or P134(a).

51. (New) The method of claim 42, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.

52. (New) The method of claim 42, wherein the method produces an improvement in FEV_1 in the patient.

53. (New) A method for treating a patient suffering from COPD, which method comprises administering to the patient, via inhalation from a pMDI, a composition comprising (i) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; (ii) a second active ingredient that is budesonide; and (iii) propellant P227, wherein the molar ratio of the first active ingredient to the second active ingredient is from 1:70 to 1:4.

54. (New) The method of claim 53, wherein the patient is administered 4.5 or 9.0 μg formoterol once or twice per day and 80 or 160 μg budesonide once or twice per day.

55. (New) The method of claim 53, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.

56. (New) The method of claim 53, wherein the method produces an improvement in FEV_1 in the patient.

Support for the new claims can be found throughout the specification as follows:

Support for new claim 26 can be found, *e.g.*, at page 11, lines 3-6. Support for new claims 27, 28, 43 and 44 can be found, *e.g.*, at page 5, lines 1-7. Support for new claims 29 and 30 can be found, *e.g.*, at page 6, lines 1-12. Support for new claims 31 and 32 can be found, *e.g.*, at page 6, lines 1-5. Support for new claims 33-35 can be found, *e.g.*, at page 5, lines 1-7. Support for new claim 36 can be found, *e.g.*, at page 6, lines 7-9. Support for new claim 37 can be found, *e.g.*, at page 6, lines 1-5. Support for new claims 38-41 and 45-48 can be found, *e.g.*, at page 4, lines 24-28. Support for new claim 42 can be found, *e.g.*, at page 4, lines 4-7, and at page 6, lines 21-22. Support for new claims 49, 50, 53, and 54 can be found, *e.g.*, at page 6, lines 1-12. Further support for new claim 53 can be found, *e.g.*, at page 4, lines 1 and 2, and further support for new claim 54 can be found, *e.g.*, at page 4, lines 24-28. Support for new claims 51 and 55 can be found, *e.g.*, at page 2, lines 9-10. Support for new claims 52 and 56 can be found, *e.g.*, at page 11, lines 8-9.

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